NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute for Regenerative Medicine
Chapter 6

Date: March 11, 2011

Deadline for Submission of Written Comment: April 25, 2011 – 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Regulations: SB 1064 Amendments to Intellectual Property Regulations

Sections Affected:

The proposed action amends sections 100607 and 100608 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and sections 125290.35, subdivisions (a), (b)(1), (2), (3), (4), (5) and (6); and 125290.40, subdivision (j), Health and Safety Code.

Reference: Sections 125290.30 and 125290.80 Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens Oversight Committee ("ICOC") is the 29-member governing board for the Institute. ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased

tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

On September 30, 2010 then-Governor Schwarzenegger signed into law Senate Bill No. 1064, which was sponsored by Senator Alquist. The law became effective January 1, 2011 and makes a number of amendments related to the California Stem Cell Research and Cures Act, commonly known as Proposition 71. The bill addressed numerous aspects of CIRM's operations. In addition, it codified, with four modifications, CIRM's revenue sharing and access plan regulations.

The four modifications were:

(1) changing the time period for submission of access plans to the ICOC;

(2) authorizing the ICOC to waive access plan requirements if certain conditions are met;

(3) changing the terminology relating to eligible recipients of access plans from "uninsured Californians" as provided for in CIRM IP regulations to "Californians who have no other means to purchase the drug"; and

(4) changing the revenue sharing regulation which levies a 1% royalty on net sales in excess of $500 million annually so that it applies only in instances where more than $5million of CIRM funding generated patented inventions or technologies that "contributed to the creation of the product" generating such revenue. Currently under CIRM's regulations the 1% royalty would apply regardless of whether the CIRM Funded Invention or CIRM Funded Technology "involved in the achievement of" the $500 million in revenue was patented or not.

The proposed regulatory action amends sections 100607 and 100608 to harmonize them with the changes made by SB 1064.

Technical, Theoretical or Empirical Studies, Reports or Documents:

A. Documents or Laws:

None.

B. Public Input:

None.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section "B" are available on CIRM's website, www.cirm.ca.gov under the "Meetings Transcripts" and "Meetings Minutes" links.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on April 25, 2011. Comments regarding this proposed action may also be transmitted via e-mail to mescomments@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than April 10, 2011.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The proposed amendments implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory action.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed action will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that this regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the regulatory action will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the proposed regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the proposed amendments to the regulations, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing, and questions about the proposed action; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

or

Amy Cheung
California Institute for Regenerative Medicine
(415) 396-9255

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact

person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at www.cirm.ca.gov.